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IN THE

Supreme Court of the United States

ALBERTO GONZALES,
Attorney General, et al.

Petitioners,

v.

STATE OF OREGON, et al.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR PROFESSORS OF LAW RICHARD BRIFFAULT, WILLIAM N. ESKRIDGE, JR., PHILIP P. FRICKEY, ELIZABETH GARRETT, JERRY L. MASHAW, EDWARD RUBIN, DAVID L. SHAPIRO, PETER L. STRAUSS, AND ERNEST A. YOUNG AS AMICI CURIAE SUPPORTING RESPONDENTS

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Amici curiae Richard Briffault, William N. Eskridge, Jr., Philip P. Frickey, Elizabeth Garrett, Jerry L. Mashaw, Edward Rubin, David L. Shapiro, Peter L. Strauss, and Ernest A. Young respectfully submit this brief supporting affirmance of the judgment below.[1]

INTEREST OF AMICI

Amici are law professors who teach and write from a range of perspectives on topics that include statutory interpretation, administrative law, legislative process, and federalism and who therefore have a professional interest in the proper application and development of law in these areas.

[1] No counsel for a party authored this brief in whole or in part, and no person or entity other than amici and their counsel made any monetary contribution toward the preparation or submission of this brief. Letters indicating the parties' consent to the filing of this brief have been submitted to the Clerk.

Richard Briffault, the Joseph P. Chamberlain Professor of Legislation and Director of the Legislative Drafting Research Fund at Columbia Law School, is the co-author of a leading casebook on state and local government law and has published widely on issues of federalism. William N. Eskridge, Jr., the John A. Garver Professor of Jurisprudence at Yale Law School, has written numerous scholarly articles on legislation and statutory interpretation and is the co-author, with Professors Frickey and Garrett, of the leading casebook and student treatise on legislation. Philip P. Frickey, the Richard W. Jennings Professor of Law at the University of California, Berkeley School of Law (Boalt Hall), has written extensively on statutory interpretation and the legislative process. Elizabeth Garrett, the Sydney M. Irmas Professor of Public Interest Law, Legal Ethics, Political Science, and Policy, Planning and Development at the University of Southern California, is the Director of the USC-Caltech Center for the Study of Law and Politics and has published widely in the areas of statutory interpretation and lawmaking. Jerry L. Mashaw, the Sterling Professor of Law at Yale Law School, is the author of numerous scholarly articles on administrative law and legislation and has co-authored a leading casebook on administrative law. Edward Rubin, the Dean and John Wade-Kent Syverud Professor of Law at Vanderbilt University Law School, has written extensively in the fields of administrative law and statutory interpretation. David L. Shapiro, the William Nelson Cromwell Professor of Law at Harvard Law School, has published widely in the areas of federalism, administrative law, and statutory interpretation. Peter L. Strauss, the Betts Professor of Law at Columbia Law School, is the co-author of a leading administrative law casebook and the author of numerous scholarly articles on administrative law and statutory interpretation. Ernest A. Young, the Judge Benjamin Harrison Powell Professor in Law at the University of Texas School of Law, has written extensively on issues of federalism and constitutional and statutory interpretation.

While this case implicates profound and difficult questions regarding end-of-life care, it is at bottom a case about determining congressional intent: this Court must determine whether the Controlled Substances Act (CSA) makes it a crime, or grants the Attorney General the power to make it a crime, for physicians to prescribe controlled substances as authorized by the Oregon Death With Dignity Act (ODWDA). Amici respectfully seek to provide the Court with a discussion of principles of statutory construction and administrative law that bear on that question.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case undoubtedly raises important issues relating to the ability of terminally ill patients to obtain the assistance of physicians in ending their lives. What should not be obscured, however, is that this case fundamentally presents a question of statutory interpretation. The threshold—and, in our view, dispositive—question before this Court is whether the Attorney General's Directive is a legitimate reading of the CSA's requirement that doctors prescribing controlled substances must act "in the course of professional practice." 21 U.S.C. § 802(21); *see id.* §§ 829, 841(a).

Two fundamental principles of statutory construction are relevant to that inquiry. *First*, the Directive's reading of the CSA contravenes the presumption that, absent a clear statement, a federal statute will not be read to preempt state law or significantly to alter the federal-state balance. Here, the Directive effectively precludes Oregon residents from exercising the option made available to them by Oregon law, preempting Oregon's choice expressly to permit the prescription of controlled substances for that purpose. And it does so by intruding into an area—the regulation of medical practice—that is "primarily, and historically, a matter of local concern." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996) (citation omitted). But the CSA—which was enacted for the very different purpose of addressing illicit drug trafficking and abuse—does not set uniform standards of medical practice for the States or authorize the Attorney General to do so. To the contrary, the CSA expressly provides that

it does not preempt state law unless that law presents a positive conflict with its terms; the relevant provisions of the CSA expressly turn in part on state law; and the CSA grants the Attorney General no authority to make scientific or medical decisions. The text, structure, and purpose of the CSA make plain that Congress did not intend to displace the States' traditional authority to regulate medical practice within their borders.

Second, the Attorney General's aggressive reading of the CSA criminalizes conduct that the CSA does not plainly prohibit. It is a "time-honored interpretive guideline," however, "that uncertainty concerning the ambit of criminal statutes should be resolved in favor of lenity." *United States* v. *Kozminski*, 487 U.S. 931, 952 (1988). The rule of lenity ensures that Congress—the most democratically accountable branch—has carefully considered whether to create a federal crime and has made a conscious judgment to do so. Because the CSA does not clearly make state-authorized physician-assisted suicide a crime or give the Attorney General the power to do so, the rule of lenity strongly counsels against the Directive's interpretation.

Both of these canons ultimately stem from respect for the democratic process in our federal system and are intended to ensure that difficult and important social questions—particularly those that affect vital state interests—are resolved through that process. They are thus particularly relevant to this case, in which Oregon voters have decided to permit their State to "serve as a laboratory," implementing the "novel social . . . experiment[]" of regulated and controlled physician-assisted suicide "without risk to the rest of the country." *New State Ice Co.* v. *Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). As this Court has observed, "[t]hroughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide." *Washington* v. *Glucksberg*, 521 U.S. 702, 735 (1997). The Directive would bring that "earnest and profound debate" to an end. Because there is no evidence Congress intended

that result, this Court should reject the Directive, permitting the people of the States to continue democratic debate and exploration of different approaches to end-of-life care.

Finally, because the Directive is not a permissible reading of the CSA, this Court need not reach the Attorney General's claim that the Directive is entitled to deference. Were it to reach that question, however, basic tenets of administrative law mandate that the Directive's novel and expansive construction of the CSA—an informal interpretive rule issued without notice and comment and purporting to resolve a morally and politically fraught question on which the Attorney General has no expertise—should receive no deference. The Attorney General's unpersuasive attempt to overreach his authority under the CSA should be rejected.

ARGUMENT

I. THE STATUTORY AND REGULATORY SCHEME

The CSA, enacted in 1970, makes it a crime to possess, distribute, or dispense a controlled substance "[e]xcept as authorized" by the statute. 21 U.S.C. § 841(a)(1). As this Court recently explained: "The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances. Congress was particularly concerned with the need to prevent the diversion of drugs from legitimate to illicit channels." *Gonzales* v. *Raich*, 125 S. Ct. 2195, 2203 (2005) (footnotes omitted).

To that end, the CSA classifies controlled substances into five "schedules." 21 U.S.C. § 812. Substances with "no currently accepted medical use in treatment in the United States" are placed in Schedule I, *id.* § 812(b)(1)(B), and may be dispensed only for extremely limited research purposes, *see id.* § 823(f). By contrast, substances with "a currently accepted medical use in treatment in the United States" are placed in Schedules II-V, *id.* § 812(b)(2)-(5), and may be dispensed by physicians to patients as authorized by the CSA.

Under the CSA, the Attorney General may decide that a substance should be controlled and place it on a particular schedule. *See id.* § 811(a); *Touby* v. *United States*, 500 U.S.

160, 162-163 (1991). Before doing so, however, he must obtain a scientific and medical evaluation of the drug from the Secretary of Health and Human Services, and he may not control the drug if the Secretary recommends against it. 21 U.S.C. § 811(b). Indeed, the Secretary's recommendations are "binding" as to all "scientific and medical matters." *Id.* The Attorney General has no authority to make medical and scientific determinations relevant to scheduling decisions.[2]

The CSA provides that substances on Schedules II-V may be dispensed by practitioners who are federally registered to do so, *see id.* § 823(f), and are acting "in the course of professional practice," *id.* § 802(21) (defining "practitioner" as one who acts "in the course of professional practice"); *see id.* § 829 (providing that "practitioners" may prescribe or dispense controlled substances).

In 1971, through notice-and-comment rulemaking, the Attorney General promulgated a regulation implementing the CSA's "course of professional practice" requirement. The regulation provides: "A prescription for a controlled substance, to be effective, must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04. A prescription not "issued . . . in the usual course of . . . professional treatment" is invalid, and writing such a prescription is a crime. *Id.*[3]

In 1994, by ballot initiative, the people of Oregon adopted the ODWDA, which provides that "[a]n adult who is capable, is a resident of Oregon, and has been determined [by two physicians] to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to die, may make a written request for medication for the purpose

[2] The Attorney General must also consider eight specified factors and comply with the notice-and-comment provisions of the Administrative Procedure Act before adding a drug to a schedule. *See* 21 U.S.C. § 811(a), (c); *Touby*, 500 U.S. at 162-163.

[3] Amici do not question the validity of the 1971 regulation.

of ending his or her life in a humane and dignified manner." Or. Rev. Stat. § 127.805(1). The statute expressly authorizes physicians to prescribe such medication if its requirements are met, *see id.* § 127.815, and provides that physicians who do so shall not "be subject to civil or criminal liability or professional disciplinary action," *id.* § 127.885(1).

After passage of the ODWDA, various persons, including then-Senator John Ashcroft, sought an opinion from then-Attorney General Janet Reno as to whether a doctor who prescribed controlled substances under the ODWDA would violate the CSA. After considering the views of parties on both sides of the question, Attorney General Reno concluded: "There is no evidence that Congress, in the CSA, intended to displace the states as the primary regulators of the medical profession, or to override a state's determination as to what constitutes legitimate medical practice . . . . [T]he CSA does not authorize DEA to prosecute, or to revoke the DEA registration of, a physician who has assisted in a suicide in compliance with Oregon law." Letter from Attorney General Reno to Rep. Henry Hyde at 4-5 (June 5, 1998).

In 2001, Ashcroft, now himself the Attorney General, reversed course by issuing the Directive, an informal interpretive rule issued without notice and comment or any consultation with Oregon and other interested parties. The Directive provides that "assisting suicide is not a 'legitimate medical purpose' within the meaning of 21 C.F.R. § 1306.04" and therefore "that prescribing, dispensing, or administering federally controlled substances to assist suicide violates" the CSA, "regardless of whether state law authorizes or permits such conduct." 66 Fed. Reg. 56,607 (Nov. 9, 2001).

II. THE DIRECTIVE IMPROPERLY PREEMPTS STATE LAW AND ALTERS THE TRADITIONAL FEDERAL-STATE BALANCE IN THE REGULATION OF MEDICAL PRACTICE

It is a well-settled principle—deriving from the most basic aspects of our federal system—that if Congress intends to preempt state law or otherwise displace state authority in an arena traditionally regulated by the States, it

will say so in plain terms. No such plain statement appears in the CSA. Rather, the text and structure of the statute make clear that Congress intended to leave the substantive regulation of the practice of medicine—including the resolution of hotly debated questions of medical ethics, such as appropriate measures for end-of-life care—where it has always primarily been, with the States. The Directive's contrary interpretation therefore cannot be sustained.

A. A Federal Statute Is Presumed Not To Preempt State Law Regulating The Practice Of Medicine

The States' primary authority to regulate the practice of medicine has been well-settled since the early days of the Republic. *See Gibbons* v. *Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824) (the police powers of the States include "[i]nspection laws, quarantine laws, [and] health laws of every description"). This Court has often reiterated that "regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 719 (1985); *see also Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 475 (1996). Indeed, establishing "standards of reasonable medical care" is a "quintessentially state-law" function. *Rush Prudential HMO, Inc.* v. *Moran*, 536 U.S. 355, 387 (2002).

This Court has often held that where "Congress [has] legislated . . . in a field which the States have traditionally occupied . . . we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). "[I]n the field of health care, a subject of traditional state regulation, there is no . . . preemption without clear manifestation of congressional purpose." *Pegram* v. *Herdrich*, 530 U.S. 211, 237 (2000); *see also, e.g., Medtronic*, 518 U.S. at 485.

The Attorney General's Directive would preempt central provisions of the ODWDA by making it a crime for doctors to prescribe controlled substances in the manner expressly authorized by the Oregon law. The Attorney General argues (Br. 44) that no preemption occurs because Oregon physicians remain free to "dispense substances other than those regulated under the CSA to hasten their patients' deaths." But every prescription written thus far under the ODWDA has been for barbiturates—Schedule II controlled substances under the CSA.[4] The Attorney General points to no way in which Oregon physicians could safely and effectively accomplish the purposes of the ODWDA without prescribing federally controlled substances. In any event, even if the Directive might leave intact some highly theoretical applications of the ODWDA, it precludes most of the statute's applications. The Attorney General's argument is therefore at best a quibble over the *scope*, not the *fact*, of preemption.

The Attorney General also contends (Br. 43) that the Directive does not preempt Oregon law because the ODWDA is still valid insofar as it exempts physicians from *state* prosecution. But this wholly misapprehends the effect of the Directive. The ODWDA expressly authorizes doctors to prescribe medications, including federally controlled substances, in accordance with its terms. Under the Supremacy Clause, however, Oregon *cannot* authorize Oregon doctors to take action that is prohibited by federal law. Thus, if the Directive validly stated federal law, its prohibition would preempt the contrary provisions of the ODWDA.

The Attorney General's contention that "States are not free to displace the federal-law duty to comply with the CSA" (Br. 44) merely begs the question. Clearly Oregon law cannot "preempt" the CSA. But the question here is the *meaning* of the CSA—and that meaning must be determined against the backdrop principle that Congress does not lightly intrude into areas traditionally regulated by the States. Nor can the Attorney General evade this principle

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[4] *See* Oregon Dep't of Human Services, *Seventh Annual Report on Oregon's Death With Dignity Act* 14 (2005).

with the claim that the Directive merely "frustrates the purposes of Oregon's voter initiative" (Br. 43). Respect for the States' sovereignty, and their primary authority over the regulation of medicine within their borders, requires that federal statutes be interpreted so as *not* to frustrate state law, absent a clear indication that Congress so intended. As shown below, *see infra* Part II.C, no such indication appears in the CSA.

B. A Federal Statute Is Presumed Not To Alter The Federal-State Balance

The basic interpretive principle that statutes are construed to respect the States' status as "independent sovereigns in our federal system," *Medtronic*, 518 U.S. at 485, extends beyond the context of preemption. Although "Congress may legislate in areas traditionally regulated by the States," this is "a power that we must assume Congress does not exercise lightly." *Gregory* v. *Ashcroft*, 501 U.S. 452, 460 (1991). Thus, "unless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance" by making law in an area historically reserved to the States. *United States* v. *Bass*, 404 U.S. 336, 349 (1971); *see also, e.g., Solid Waste Agency of N. Cook County* v. *United States Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001); *BFP* v. *Resolution Trust Corp.*, 511 U.S. 531, 544 (1994). This clear statement rule "assures that [Congress] has in fact faced, and intended to bring into issue, the critical issues involved" when it legislates in an area traditionally reserved to the States. *Bass*, 404 U.S. at 349.

The Attorney General mistakenly contends (Br. 38-39) that the Directive does not implicate this rule because it does not reach to the core of state sovereignty. Although *Gregory* v. *Ashcroft* applied the rule to avoid federal interference with state law establishing the qualifications of state judges, *see* 501 U.S. at 460, the rule's application is not limited to such circumstances. Rather, as both *Bass* and *BFP* make clear, the rule applies whenever a federal statute "would mark a major inroad into a domain traditionally left to the States." *Bass*, 404 U.S. at 339 (applying rule to hold

that federal criminal statute did not criminalize conduct already made a crime by state law). "Federal statutes impinging upon important state interests 'cannot . . . be construed without regard to the implications of our dual system of government.'" *BFP*, 511 U.S. at 544 (citation omitted). Congress may override state law in an area traditionally regulated by the States when it does so unambiguously; "[b]ut where the intent to override is doubtful, our federal system demands deference to long-established traditions of state regulation." *Id.* at 546.

The question in *BFP* was the meaning of the phrase "reasonably equivalent value" in the Bankruptcy Code's fraudulent transfer provisions. This Court held that, when property is sold at a foreclosure sale conducted in accordance with state law, whatever price is thereby obtained is "reasonably equivalent value." *See BFP*, 511 U.S. at 545. The Court reasoned that interpreting "reasonably equivalent value," as the court of appeals had done, to "specify a federal 'reasonable' foreclosure-sale price," *id.* at 540, would cast a cloud on the title of much foreclosed property, frustrating state law in an area historically the province of the States. *See id.* at 544. Because the statute evinced no "clear and manifest" intent "[t]o displace traditional state regulation in such a manner," it would not be read to do so. *Id.*

This case presents very similar concerns. The Attorney General's interpretation of the CSA directly impinges on an important state interest in an area traditionally regulated by the States. The purpose of the clear statement rule is to preserve a "federalist structure of joint sovereigns . . . that will be more sensitive to the diverse needs of a heterogeneous society" and that "increases opportunity for citizen involvement in democratic processes; [and] allows for more innovation and experimentation in government." *Gregory*, 501 U.S. at 458. That purpose is plainly implicated here. The Directive not only intrudes upon a realm historically the province of the States, but goes much further—it purports to resolve complex moral questions regarding end-of-life care, questions that are the subject of "an earnest and pro-

found debate" among the people of the States. *Washington* v. *Glucksberg*, 521 U.S. 702, 735 (1997). Before adopting such an interpretation of a statute whose primary purpose was to address quite different questions, it is appropriate to take great care to ensure that Congress intended that result.

C. The CSA Does Not Authorize The Attorney General To Set Uniform Standards Of Medical Practice For The States

1. The CSA contains no indication—clear or otherwise—that Congress intended to grant the Attorney General the power to set uniform federal standards of medical practice for the States. To the contrary, the CSA expressly states that it should *not* be construed to override state law unless the conflict between the text of the CSA and state law is plain. *See* 21 U.S.C. § 903 ("No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field . . . to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision . . . and that State law so that the two cannot consistently stand together."). There is no such positive conflict here.

Indeed, from the beginning, the CSA has looked to state law to determine which persons are "practitioners" acting "in the course of professional practice" and are thus eligible for federal registration to dispense controlled substances. The very definition of "practitioner" under the CSA turns in part on state law, providing that a "practitioner" includes "a physician . . . licensed . . . by the United States *or the jurisdiction in which he practices* . . . to . . . dispense . . . a controlled substance *in the course of professional practice*." 21 U.S.C. § 802(21) (emphasis added). That provision clearly contemplates that state law will inform the contours of "the course of professional practice" for purposes of the CSA.

The CSA's registration provisions also expressly recognize the primacy of state law in determining the circumstances under which controlled substances may properly be dispensed. The statute provides that "[t]he Attorney General shall register practitioners . . . to dispense . . . controlled substances in Schedule II, III, IV, or V, *if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.*" *Id.* § 823(f) (emphasis added). Under the CSA as originally enacted, registration was "a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law." H.R. Rep. No. 91-1444, pt. 1, at 23 (1970). The Attorney General was authorized to revoke or suspend a registration only if the registrant had materially falsified his application, had been convicted of a felony relating to controlled substances, or "had his State license or registration suspended, revoked, or denied by competent State authority." Pub. L. No. 91-513, § 304(a), 84 Stat. 1236, 1255 (1970).

In 1984, Congress amended the CSA's registration provisions in order to address "the problem of diversion of dangerous drugs" into the hands of drug abusers, against which "many States [had been] unable to take effective or prompt action."[5] As amended, the statute continues to provide that practitioners licensed by the State in which they practice are presumptively entitled to registration. *See* 21 U.S.C. § 823(f). The Attorney General may deny, suspend, or revoke a registration of a state-licensed practitioner if doing so is in "the public interest." *Id.* In determining the "public interest," however, the Attorney General must consider five factors, the first of which is "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority." *Id.* § 823(f)(1).[6] The statute itself thus

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[5] S. Rep. No. 98-225, at 266 (1983); *see also id.* at 266-267 (citing, as a key reason for the amendment, "delays in obtaining conviction" under state law of doctors who have "abused their authority to dispense controlled substances").

[6] Two other factors also turn in part on state law—"[t]he applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances," *id.* § 823(f)(3), and "[c]ompliance with applicable State, Federal, or local laws relating to controlled substances," *id.* § 823(f)(4).

makes clear that the Attorney General is still expected to defer to the views of state licensing authorities, and that Congress did not intend to override the States' primary authority to regulate medical practice.[7] Congress's objective in amending the statute was much narrower: to ensure that doctors acting as drug dealers would not retain their federal registration merely because state authorities failed adequately to enforce state law.

The statute makes clear that, had Congress intended to impose a uniform federal standard for medical practice, it knew how to do so. The CSA does expressly contemplate uniform federal standards in one narrow area: the treatment of narcotics addiction. *See* 42 U.S.C. § 290bb-2a ("The Secretary of Health and Human Services, after consultation with the Attorney General . . . shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts . . . ."). Notably, however, the authority to devise this standard was given to the Secretary, *not* the Attorney General, whom Congress has consistently declined to entrust with medical decisions. *See id.*[8] Congress's explicit decision to permit the Secretary to create uniform federal standards in this narrow area, combined with its more general reluctance to displace state regulation of medical practice, show that Congress did not empower the Attorney General to override state regulation of medical practice in other areas.

[7] The legislative history confirms what the text makes plain: "the amendment would continue to give deference to the opinions of State licensing authorities, since their recommendations are the first of the factors to be considered with respect to practitioner applications." S. Rep. No. 98-225, at 267.

[8] The Attorney General's reliance on these provisions (Br. 32-33) is accordingly misplaced; they demonstrate not that Congress intended to give the Attorney General the power to set uniform standards of medical practice for the States in all contexts, but rather that it intended to give the *Secretary* the power to do so in one specific narrow context. *See* H.R. Rep. No. 91-1444, at 15 (expressing "concern[] about the appropriateness of having Federal officials determine the appropriate method of the practice of medicine," but opining that it was necessary to set uniform federal standards in that specific area in order to address doctors' unwillingness to accept drug addicts as patients).

2. In the face of this powerful evidence that Congress did not intend to give the Attorney General the power to displace the States' long-standing regulatory authority over the practice of medicine, the Attorney General first argues (Br. 18-19) that the statute's "course of professional practice" requirement, 21 U.S.C. § 802(21), itself clearly prohibits the prescription of controlled substances for the purpose of physician-assisted suicide. But that phrase, on its face, is certainly broad enough to encompass any medical practice expressly authorized by state law. Indeed, this Court has interpreted the "course of professional practice" standard to mean only that, when prescribing controlled substances, a doctor must be acting in the service of what he believes to be the good of his patients, rather than some other goal, such as personal gain. That is, a doctor must be acting *as a doctor* and not as a drug dealer. Thus, in *United States* v. *Moore*, this Court held that a doctor violated the CSA by prescribing controlled substances "not for legitimate purposes, but 'primarily for the profits to be derived therefrom,'" 423 U.S. 122, 135 (1975), and thus "act[ing] as a large-scale 'pusher' not as a physician," *id.* at 143.[9]

Lacking any more persuasive evidence in the text of the statute, the Attorney General falls back on the argument (Br. 18-19) that dictionary definitions of the word "medicine" exclude physician-assisted suicide as a "legitimate medical purpose"—the phrase employed by the regulation. But, as

[9] Similarly, this Court's decision in *Webb* v. *United States*, 249 U.S. 96 (1919)—relied on by the Attorney General (Br. 19)—held that a doctor who sold morphine to addicts solely to assist them in satisfying their addiction was not acting in the course of professional practice within the meaning of the Harrison Act, the predecessor to the CSA. *See* 249 U.S. at 97. Neither case remotely suggests that the CSA intended to go beyond criminalizing the illicit distribution of drugs for profit to supersede the States' authority to define the practice of medicine.

the Attorney General himself acknowledges (Br. 17 n.6), the regulation's "legitimate medical purpose" standard merely restates the statute's "course of professional practice" requirement. It does not—and indeed could not—criminalize conduct not reached by the terms of the CSA itself.

In any event, the Attorney General's wooden recitation of dictionary definitions does not support his view that the CSA empowers him to make physician-assisted suicide a crime. The definitions of "medicine" that he cites—which include "alleviation" of "disease" (Br. 19)—are not inconsistent with the position that the end-of-life care authorized by the Oregon statute is a legitimate medical practice. More importantly, the boundaries of legitimate medical practice raise scientific and moral questions far too complex to be resolved by invoking the dictionary. "[T]he good physician is not just a mechanic of the human body whose services have no bearing on a person's moral choices, but one who does more than treat symptoms, one who ministers to the patient.... This idea of the physician as serving the whole person is a source of the high value traditionally placed on the medical relationship." *Glucksberg*, 521 U.S. at 779 (Souter, J., concurring in the judgment). Nothing in either the CSA or the regulation suggests otherwise, or intimates that Oregon may not permit doctors, in the course of their professional practice, to assist a terminally ill person to control the circumstances of his death.[10]

[10] The Attorney General's contention (Br. 19-20) that the CSA's legislative history reveals an intention to prohibit the use of controlled substances in connection with physician-assisted suicide is equally misguided. The only reference to suicide in the House and Senate Reports occurs in the context of a discussion concerning intentional and accidental overdoses resulting from use *contrary* to or without professional advice, H.R. Rep. No. 91-1444, at 35 (1970), not in accordance with it. Notably, in 1998 and again in 1999, Congress rejected legislation that would have expressly extended the CSA to physician-assisted suicide. H.R. 4006, 105th Cong. (1998) ("Lethal Drug Abuse Prevention Act of 1998"); H.R. 2260, 106th Cong. (1999) ("Pain Relief Promotion Act of 1999").

3. The Attorney General next contends that the CSA must establish uniform standards for medical practice because "'in the absence of a plain indication to the contrary, ... Congress when it enacts a statute is not making the application of the federal act dependent on state law.'" Pet. Br. 25 (quoting *Mississippi Band of Choctaw Indians* v. *Holyfield*, 490 U.S. 30, 43 (1989)). But this "general assumption," *Holyfield*, 490 U.S. at 43, is simply inapplicable here, because the CSA contains several "plain indication[s] to the contrary": Congress defined "practitioner" in part by reference to state law; required that the Attorney General consider state law in registering practitioners to dispense controlled substances; and chose explicitly to adopt a uniform federal standard concerning the treatment of drug addicts, while declining to do so for any other area of medical practice.[11] Congress clearly contemplated that the application of the CSA in regulating physicians would vary from state to state.

Neither *United States* v. *Moore* nor *United States* v. *Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001) (discussed at Pet. Br. 28-32), supports a contrary conclusion. *Moore* confirmed that the CSA "limit[s] a registered physician's dispensing authority to the course of his 'professional practice.'" 423 U.S. at 140. Because Moore "concede[d] in his brief that he did not observe generally accepted medical practices," *id.* at 126, however, this Court had no occasion to consider whether the CSA generally was intended to displace state determinations of what constitutes "professional

[11] It is not rare for Congress to make the application of a federal statute dependent on state law, even without saying so expressly. *See, e.g.*, *BFP*, 511 U.S. at 544 (holding that the term "reasonably equivalent value" in the Bankruptcy Code's fraudulent transfer provisions implicitly incorporates state-law standards in the context of foreclosure sales); *Helvering* v. *Stuart*, 317 U.S. 154, 161-162 (1942) (holding that the "necessary implication" of federal tax statute is that conditions for taxing trust assets depend on state property law, because "[t]he power to transfer or distribute assets of a trust is essentially a matter of local law").

practice."[12] Indeed, as discussed above, *Moore* held that the application of the CSA "turn[s] on whether the 'transaction' falls within or without legitimate channels" of distribution—that is, whether the doctor was "act[ing] as a . . . 'pusher' not as a physician." *Id.* at 135, 143. *Moore* provides no support for the Attorney General's notion that the CSA sets substantive standards for medical practice where, as here, a doctor is *not* acting as a drug dealer.[13]

Oakland Cannabis is similarly unhelpful to the Attorney General. There, this Court held that, because marijuana is a Schedule I drug with "'no currently accepted medical use,'" 532 U.S. at 491 (quoting 21 U.S.C. § 812(b)(1)(B)), "medical necessity is not a defense" to the CSA's prohibition of its manufacture and distribution, *id.* at 494. In other words, *Oakland Cannabis* involved a state law that—unlike the ODWDA—*did* create a "positive conflict," 21 U.S.C. § 903, with the express terms of the CSA.

The Attorney General argues (Br. 29-30) that because he could "reclassify the Schedule II substances typically used by Oregon physicians to assist suicide to Schedule I if the medical and scientific evidence warranted," he must also have the authority to override the States' judgment regarding which uses of Schedule II substances are medically acceptable. This greater-power-includes-the-lesser logic is flawed, because there is an important difference in the nature of federal authority with respect to Schedule I drugs

[12] Moreover, *Moore* dealt with the distribution of methadone ostensibly to treat heroin addicts, *id.* at 125-127—the one context in which the CSA does seek to establish uniform federal standards for medical practice.

[13] The court of appeals decisions on which the Attorney General relies (Br. 32) similarly involved doctors "not acting in good faith as . . . doctor[s], but simply pushing pills" for profit. *United States* v. *Rosenberg*, 515 F.2d 190, 197 (9th Cir. 1975). Although *Rosenberg* rejected the defendant's claim that the federal government could not constitutionally regulate medical practice and thus could not convict him absent a prior state conviction, neither *Rosenberg* nor any of the other decisions suggests that a doctor could act outside "the course of professional practice" by engaging in a medical practice expressly authorized by state law.

and drugs on other schedules. A drug on Schedule I has been federally determined to have "no currently accepted medical use in treatment in the United States," 21 U.S.C. § 812(b)(1)(B), and thus no state has the power to create or approve such a use (as this Court held in *Oakland Cannabis*). Drugs on other schedules, however, have accepted medical uses and may be dispensed to patients by practitioners acting "in the course of professional practice." *Id.* § 802(21). As discussed above, the CSA contemplates that the Attorney General will defer to the States' primary authority to regulate the "professional practice" of medicine.

Indeed, even with respect to classification, the CSA expressly refuses to grant the Attorney General the authority to make medical and scientific determinations—instead giving that power solely to the Secretary of Health and Human Services. *See id.* § 811(b). This provision reflects Congress's common-sense recognition that, as a law enforcement official, the Attorney General has no scientific or medical expertise and thus should not be given the power to decide such questions. The Attorney General's construction of the CSA—under which the statute expressly precludes him from making medical determinations relating to classification, yet implicitly grants him the power to set standards of medical practice for the States—is simply implausible.

III. THE RULE OF LENITY COUNSELS AGAINST THE ATTORNEY GENERAL'S INTERPRETATION OF THE CSA

Under the Attorney General's novel and aggressive interpretation of the CSA, a doctor commits a crime—and is subject to criminal penalties, as well as the loss of federal registration—when he prescribes controlled substances for a medical purpose expressly authorized by Oregon law. As demonstrated above, the CSA does not permit that construction. Even if the CSA were unclear on this point, however, it is a "time-honored interpretive guideline that uncertainty concerning the ambit of criminal statutes should be resolved in favor of lenity." *United States* v. *Kozminski*, 487 U.S. 931, 952 (1988). When confronted with "two rational readings of a criminal statute, one harsher than the other,

we are to choose the harsher only when Congress has spoken in clear and definite language." *McNally* v. *United States*, 483 U.S. 350, 359-360 (1987); *see also, e.g.*, *Crandon* v. *United States*, 494 U.S. 152, 158 (1990).

The rule of lenity—an application of the fundamental principle *nulla poena sine lege*[14]—is a means of effectuating Congress's intent. It presumes that, if Congress has not clearly stated its decision to make a particular act a crime, it likely has not carefully weighed the considerations that would inform that decision. "[B]ecause of the seriousness of criminal penalties, and because criminal punishment usually represents the moral condemnation of the community, legislatures"—and not courts or prosecutors—"should define criminal activity." *Bass*, 404 U.S. at 348; *see also, e.g.*, *Whalen* v. *United States*, 445 U.S. 684, 689 (1980) ("[W]ithin our federal constitutional framework . . . the power to define criminal offenses . . . resides wholly with the Congress."). By requiring Congress to speak "in clear and definite language," *McNally*, 483 U.S. at 360, the rule of lenity ensures that Congress has in fact made a considered decision to make the conduct at issue a crime. As shown above, *see supra* Part II, the CSA contains no language authorizing the Attorney General to regulate medical practice, much less to make this particular instance of medical practice a federal crime. The Directive thus improperly arrogates to the chief federal prosecutor—contrary to the most basic principles governing criminal law—the power to define a crime.

The rule of lenity plays a particularly vital role where, as here, the government's proposed expansive interpretation of a federal criminal statute would intrude on areas traditionally regulated by the States. In such a situation, it is even less likely that Congress would have intended to create a crime by implication. Thus, in *Bass*, this Court held that,

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[14] *See, e.g.*, *Rogers* v. *Tennessee*, 532 U.S. 451, 467-468 (2001) (Scalia, J., dissenting) (noting that the maxim "'dates from the ancient Greeks and has been described as one of the most 'widely held value-judgment[s] in the entire history of human thought'" (citation omitted)).

where the government's interpretation of a criminal statute would "significantly change[] the federal-state balance," it is especially appropriate to require that Congress have spoken clearly before adopting that interpretation. *Bass*, 404 U.S. at 349. Similarly, in *Cleveland* v. *United States*, the Court adopted a narrow reading of the federal mail fraud statute because a broader interpretation would "subject to federal mail fraud prosecution a wide range of conduct traditionally regulated by state and local authorities." 531 U.S. 12, 24 (2000). And in *McNally*, the Court applied the rule of lenity to construe the federal mail fraud statute not to reach a scheme by state officials to deprive victims of an intangible right to honest government, because that reading would intrude on a realm that is primarily the province of the States. *See* 483 U.S. at 360.

The rule of lenity applies here even though the Attorney General may choose not to pursue criminal prosecution. *See, e.g.*, *Leocal* v. *Ashcroft*, 125 S. Ct. 377 (2004). In *Leocal*, this Court held that it was "constrained to interpret any ambiguity in the statute in [the defendant's] favor" because, even though the statute was not being used in a criminal context, "it has both criminal and noncriminal applications. Because we must interpret the statute consistently, whether we encounter its application in a criminal or noncriminal context, the rule of lenity applies." *Id.* at 384 n.8; *see also Crandon*, 494 U.S. at 158 (even for a civil penalty "set forth in a criminal statute, it is appropriate to apply the rule of lenity in resolving any ambiguity in the ambit of the statute's coverage"); *United States* v. *Thompson/Center Arms Co.*, 504 U.S. 505, 517-518 (1992) (plurality opinion) (applying rule of lenity to a tax statute construed in a civil setting because the statute also created criminal liability); *id.* at 519 (Scalia, J., concurring in the judgment) (same).

Because the Attorney General's interpretation of the CSA creates criminal liability where there is no evidence that Congress intended to make the conduct at issue a crime

or to grant the Attorney General the power to do so, the rule of lenity counsels that it should be rejected.[15]

IV. THE CSA SHOULD NOT BE READ TO PRECLUDE DEMOCRATIC DEBATE AND EXPLORATION OF DIFFERENT APPROACHES BY THE STATES ON THE QUESTION OF PHYSICIAN-ASSISTED SUICIDE

Both the presumption that Congress will not casually intrude into an area traditionally the province of the States and the rule of lenity ultimately derive from respect for the democratic process in our Federal system. Those canons give effect to the principle that certain questions are particularly inappropriate for resolution by courts and prosecutors, and that it is thus particularly critical to ensure that Congress, as the most democratically accountable branch, has carefully considered and clearly resolved them.

That is especially true in this case. The Directive purports to resolve the hotly disputed scientific, medical, and, at bottom, moral question whether physician-assisted suicide can ever be a part of legitimate medical practice. Less than ten years ago, in *Washington* v. *Glucksberg*, this Court disclaimed the institutional competence to resolve that question, concluding that it should be answered through the democratic process. *See* 521 U.S. at 735.

[15] To be sure, as the Court observed in a footnote in *Babbitt* v. *Sweet Home Chapter of Communities for a Great Oregon*, the rule of lenity does not necessarily "provide the standard for reviewing facial challenges to administrative regulations" in every case where "the governing statute authorizes criminal enforcement." 515 U.S. 687, 704 n.18 (1995). In other words, *Sweet Home* observed that the rule of lenity will not always trump *Chevron* deference, where such deference is appropriate. In that case, unlike this one, *Chevron* deference was due because the agency had been delegated, and had exercised, rulemaking authority to create the standards at issue. *See id.* at 703. As demonstrated below, *see infra* Part V, no such deference is warranted here; the question is simply whether the CSA makes it a crime, or empowers the Attorney General to make it a crime, to prescribe drugs as authorized by the ODWDA. As a long-established tool for determining congressional intent in criminal statutes and a settled part of the interpretive background against which Congress legislates, the rule of lenity is obviously relevant to that inquiry.

As *Glucksberg* explained, "Americans today are increasingly likely to die in institutions, from chronic illnesses. Public concern and democratic action are therefore sharply focused on how best to protect dignity and independence at the end of life ...." 521 U.S. at 716 (citation omitted). "Thus, the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide." *Id.* at 719. The Court specifically noted Oregon's choice to permit physician-assisted suicide "for competent, terminally ill adults." *Id.* at 717. And the Court's ultimate decision not to recognize a broad due process right to assistance in committing suicide rested in part on its reluctance to cut off that democratic debate and exploration of different approaches among the States: "Throughout the Nation, Americans are engaged in an earnest and profound debate about the morality, legality, and practicality of physician-assisted suicide. Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735.

Justice O'Connor's concurrence similarly noted: "As the Court recognizes, States are presently undertaking extensive and serious evaluation of physician-assisted suicide and other related issues.... In such circumstances, 'the ... challenging task of crafting appropriate procedures for safeguarding ... liberty interests is entrusted to the "laboratory" of the States ... in the first instance.'" 521 U.S. at 737 (O'Connor, J., concurring) (citations omitted). And Justice Souter expressly rested his concurrence in the judgment on the proposition that the Court "should ... stay its hand to allow reasonable legislative consideration" of the issue of physician-assisted suicide. *Id.* at 789 (Souter, J., concurring in the judgment). He reasoned that only "experimentation in some jurisdictions" can "confirm[] or discredit[] the concerns" about possible abuse of physician-assisted suicide, and anticipated that the Court's restraint would open the

door for "just such experimentation [to] be attempted in some of the States." *Id.* at 787-788 (citing the ODWDA).[16]

These same considerations counsel strongly against interpreting the CSA to permit an unelected executive official, via administrative fiat, to foreclose all such exploration by the States. In Justice Brandeis' famous words:

> To stay experimentation in things social and economic is a grave responsibility. Denial of the right to experiment may be fraught with serious consequences to the nation. It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.

New State Ice Co. v. *Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting).

Only efforts like Oregon's can resolve the "serious factual controversy" over the wisdom and feasibility of regulated physician-assisted suicide—and, ultimately, the constitutional question of the proper balance between the governmental interest in protecting the disabled and vulnerable and the individual's interest in avoiding suffering and loss of dignity at the end of life. *Glucksberg*, 521 U.S. at 786 (Souter, J., concurring in the judgment); *see also id.* at 737 (O'Connor, J., concurring). The Directive would eliminate the only opportunity to learn, through experience with various approaches to regulation and monitoring of physician-

[16] In *Glucksberg*, the Department of Justice advocated this cautious approach, arguing that state legislatures, rather than the federal government, should determine whether the terminally ill should be permitted to request life-ending medication. *See* Br. of United States as Amicus Curiae Supporting Petitioners, *Washington* v. *Glucksberg* (1996), 1996 WL 663185, at *10 ("Because terminal illness potentially affects all Americans . . . there is every reason to believe that state legislatures will address the urgent issues involved in this case in a fair and impartial way."); *id.* at *27 n.3 ("States have begun to consider anew the issue of physician assisted suicide, and there is no indication that the political processes are malfunctioning.") (citing Oregon's approval of the ODWDA).

assisted suicide, whether opponents' concerns about its use are valid, and which approach best accommodates the deeply important interests implicated. Oregon's choice to permit regulated physician-assisted suicide in limited circumstances, on the other hand, provides the chance to obtain experience and empirical data that can help answer those questions.[17]

This Court's task, of course, is not to evaluate the wisdom of Oregon's choice, but to determine whether the CSA precludes it from making that choice. That task of statutory interpretation should be informed by a recognition of the Directive's effect. The Attorney General's expansive construction of his own power under the CSA would prematurely cut off democratic exploration and debate among the States on the difficult questions surrounding end-of-life care—and it would do so by making doctors' compliance with the ODWDA a federal crime. Basic principles of statutory construction support the view that if Congress had intended to take such a radical step—or to grant the Attorney General the authority to do so—it would have given a clearer indication of its intent than the Attorney General can find in the CSA. Because the Attorney General's reading is not authorized by the CSA, this Court should decline to adopt it, and instead permit the debate over physician-assisted suicide "to continue, as it should in a democratic society." *Glucksberg*, 521 U.S. at 735.

[17] The ODWDA requires detailed recordkeeping by physicians, *see* Or. Rev. Stat. § 127.855, and requires that the Oregon Department of Health Services prepare an annual report analyzing the state's experience with the ODWDA, *see id.* § 127.865. Oregon Health Services has thus far issued seven such annual reports, which contain detailed information on the demographic characteristics of the patients who requested prescriptions under the ODWDA and the reasons for their choice. *See* Oregon Dep't of Human Services, *Seventh Annual Report on Oregon's Death with Dignity Act* (2005). These reports are a valuable source of information about the experience of legalized, regulated physician-assisted suicide.

V. THE ATTORNEY GENERAL'S DIRECTIVE WARRANTS NO DEFERENCE

Because, for all the reasons given above, the Directive is not a permissible construction of the CSA, this Court need not reach the Attorney General's contention (Br. 21) that the Directive deserves deference.[18] Even if the Court were to conclude that the Attorney General's interpretation is not precluded by the CSA, however, the Court should reject his claim to deference—and, for the reasons above, should find his reading of the statute unpersuasive.

Although the Attorney General now invokes *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Directive—an interpretive rule issued without notice and comment, on a subject as to which the Attorney General has no relevant expertise—is very far from the type of agency pronouncement entitled to *Chevron* deference.[19] Such deference is warranted only when "Congress delegated authority to the agency generally to make rules carrying the force of law," such as by "adjudication or notice-and-comment rulemaking," and when "the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States* v. *Mead Corp.*, 533 U.S. 218, 226-227 (2001). "It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *Id.* at 230.

That test is not met here. The Directive was issued not only without notice and comment, but without any other

[18] *See MCI Telecommunications Corp.* v. *AT&T*, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear . . . .").

[19] Indeed, in the proceedings below, the Attorney General did not even attempt to claim *Chevron* deference, instead arguing only for the lesser standard of deference articulated in *Skidmore* v. *Swift & Co.*, 323 U.S. 134 (1944). *See* Ashcroft App. Br. 23-24.

procedural formalities that would "tend[ ] to foster . . . fairness and deliberation." 533 U.S. at 230. The Directive relies solely on a memorandum from the Office of Legal Counsel of which Oregon was given no notice, and to which it was given no opportunity to respond. Nor is there any indication in the CSA that Congress intended to confer the kind of broad authority that would warrant deference in the absence of notice-and-comment procedures.[20] The Directive thus presents "a case far removed not only from notice-and-comment process, but from any other circumstances reasonably suggesting that Congress" would have intended the Directive to enjoy *Chevron* deference. *Id.* at 231.

Accordingly, the Directive should receive only whatever deference is due under *Skidmore* v. *Swift & Co.*, 323 U.S. 134 (1944). *See, e.g., Mead*, 533 U.S. at 234; *Christensen* v. *Harris County*, 529 U.S. 576, 587 (2000). Under *Skidmore*, the degree of deference afforded an agency pronouncement "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade." 323 U.S. at 140.

The Directive fails when judged against these criteria. *First*, the Directive bears no hallmarks of the kind of deliberative process that would entitle it to respect. The Attorney General did not inform Oregon of his deliberations, solicit Oregon's views, or take into account the empirical data Oregon had collected in the four years that the ODWDA had been in effect. *Second*, "[a]n agency interpretation . . . which conflicts with the agency's earlier interpretation is 'entitled to considerably less deference' than a consistently held

[20] By contrast, Congress specifically provided elaborate procedures for altering the schedule of controlled substances—provisions that, as this Court recognized in *Touby*, rendered tolerable the statute's grant of authority to the Attorney General, within the bounds set by the CSA, to make rules that render criminal the possession and distribution of such substances. *See* 500 U.S. at 166-167. The absence of similar procedures here is compelling evidence that no such power was contemplated.

agency view." *INS* v. *Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (citation omitted). Here, the Directive represents a recent and sharp reversal of course from the previous Attorney General's views. *See supra* Part I. *Third*, the Attorney General has no relevant scientific or medical expertise that would entitle him to deference on the question whether physician-assisted suicide is a legitimate medical practice, *see Mead Corp.*, 533 U.S. at 235—indeed, Congress has expressly refused to give the Attorney General the power to resolve scientific or medical questions under the CSA, instead assigning that authority to the Secretary of Health and Human Services, *see* 21 U.S.C. § 811(b).

The Attorney General erroneously contends, relying on *Auer* v. *Robbins*, 519 U.S. 452 (1997), that he is entitled to a particularly high degree of deference because the Directive interprets both the CSA and the 1971 regulation. As the Attorney General acknowledges (Br. 5, 17 n.6), however, the regulation's "legitimate medical purpose" standard merely restates the statute's "course of professional practice" requirement. The question is therefore whether the Directive is a permissible interpretation of the *statute*. It would make no sense, in resolving that question, to give the Attorney General greater deference than he would otherwise receive, simply because of the existence of a regulation that echoes the statutory standard.

As *Auer* itself makes clear, the primary justification for special deference to an agency's interpretation of its own regulation is that, as the drafter of the regulation, the agency is in the best position to know what it means. *See* 519 U.S. at 461 (finding that deference was due because the concept at issue was "a creature of the Secretary's own regulations"); *see also, e.g.*, *Martin* v. *OSHRC*, 499 U.S. 144, 152-153 (1991). Similarly, where the regulation being interpreted is part of "'a complex and highly technical regulatory program'" established by the agency, the agency has special relevant expertise entitling its views to respect. *Thomas Jefferson Univ.* v. *Shalala*, 512 U.S. 504, 512 (1994) (citation omitted). Neither justification for special deference has any

force here, where the regulation merely restates the statutory standard, and Congress has refused to give the Attorney General the power to resolve medical and scientific questions of the kind addressed by the Directive.[21]

Finally, whatever standard is applied, the very nature of the question that the Directive purports to resolve counsels strongly against granting the Attorney General the deference he seeks. As the Court has explained, "we must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of [great] economic and political magnitude to an administrative agency." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (holding that the Food, Drug, and Cosmetic Act did not grant the FDA the authority to regulate tobacco products). The more important and politically fraught the question, the less likely it is that Congress would grant an agency the power to resolve it without making the delegation of authority clear. *See id.*; *see also MCI*, 512 U.S. at 231; *Kent* v. *Dulles*, 357 U.S. 116, 129 (1958). Put another way, "Congress does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (holding that, for the Clean Air Act to grant the EPA authority to consider costs in setting air quality standards, the "textual commitment must be a clear one" and finding no

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[21] As several Justices have noted, application of the *Auer* rule may in some cases "disserve[] the very purpose behind the delegation of lawmaking power to administrative agencies" by giving the agency an incentive to promulgate vague regulations and supply the necessary detail through procedures that lack the constraints imposed by notice-and-comment rulemaking. *Thomas Jefferson Univ.*, 512 U.S. at 525 (Thomas, J., dissenting, joined by Stevens, O'Connor, and Ginsburg, JJ.); *see generally* John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 Colum. L. Rev. 612, 618, 654-660 (1996). That concern is even more powerful here, where the interpretation of the regulation criminalizes conduct not clearly made a crime by either the statute or the regulation.

such clear delegation of authority). That is particularly true where, as here, the agency's assertion of power "alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste*, 531 U.S. at 173 (refusing to grant *Chevron* deference to an administrative interpretation of a statute that altered the federal-state balance).

These principles should govern here. Physician-assisted suicide is precisely the kind of important and divisive political question that Congress does not delegate to an administrative agency by implication. Yet the Directive arrogates to a single unelected executive official the authority to decide that question and to cut short the democratic debate on end-of-life care among the States. Only a much clearer statement would justify the conclusion that Congress intended to take such a momentous step. Because the CSA does not grant the Attorney General the power to resolve the profound medical, political, and moral questions posed by physician-assisted suicide, the Directive should be rejected.

CONCLUSION

The judgment of the United States Court of Appeals for the Ninth Circuit should be affirmed.

Respectfully submitted,

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